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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jennifer L. West and Brenda K. Mann

Serial No.: 09/935,168 Art Unit: 1644

Filed: August 21, 2001 Examiner: Phuong Huynh

For: *TISSUE ENGINEERING SCAFFOLD PROMOTING MATRIX PROTEIN PRODUCTION*

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Responsive to the Office Action mailed on September 24, 2002, please consider the following remarks. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

The Restriction Requirement

In the Office Action mailed September 24, 2002, the 23 claims were divided into nine groups:

Group I, claims 1, 2, and 6-9, drawn to a method for making a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold wherein the matrix enhancing molecule is TGFβ (Class 623, subclass 11)

Group II, claims 1-3 and 6-8, drawn to a method for making a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold wherein the matrix enhancing molecule is angiotensin II (Class 623, subclass 11)

Group III, claims 1, 2, 4, and 6-8, drawn to a method for making a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold wherein the matrix enhancing molecule is insulin-like growth factor (Class 623, subclass 11)

Group IV, claims 1,2, and 5-8, drawn to a method for making a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold wherein the matrix enhancing molecule is ascorbic acid (Class 623, subclass 11)

Group V, claims 10-15, drawn to a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix enhancing molecule is TGFβ (Class 530, subclasses 355 and 350)

Group VI, claims 16, 17, and 21-23, drawn to a method for repair or replacement of tissue comprising applying or implanting at a site in need of repair a tissue engineering scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit

production of extracellular matrix without increasing cellular proliferation wherein the matrix-enhancing molecule is TGFβ (Class 424, subclass 422)

Group VII, claims 16, 18, and 21-23, drawn to a method for repair or replacement of tissue comprising applying or implanting at a site in need of repair a tissue engineering scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix-enhancing molecule is TGFβ (Class 424, subclass 423)

Group VIII, claims 16, 19, and 21-23, drawn to a method for repair or replacement of tissue comprising applying or implanting at a site in need of repair a tissue engineering scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix-enhancing molecule is insulin-like growth factor (Class 424, subclass 423)

Group IX, claims 16, 20, and 21-23, drawn to a method for repair or replacement of tissue comprising applying or implanting at a site in need of repair a tissue engineering scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix-enhancing molecule is ascorbic acid. (Class 424, subclass 423)

In response, the Applicants elect Group I, claims 1, 2, and 6-9 with traverse.

The Restriction Requirement is Improper

The restriction requirement is improper for two reasons:

(1) The independent claims are generic and the restriction requirement significantly narrows the scope of the claims absent any prior art or opportunity to argue that the claims are patentable. The examiner has no right to narrow the claims; only to identify prior art which goes to the issue of novelty and non-obviousness and to raise issues under 35 U.S.C. 112.

At most, the examiner should be entitled to require an election of species.

(2) The MPEP provides that product and method of manufacture claims should be examined together unless there are elements present in the method of manufacture claims that are different from those in the product claims.

The Independent Claims are Drawn to a Genus

The claims are structured in a genus- species relationship as defined by MPEP 806.04. Claims 1, 2, 6, 10, 11, 16, 21, 22 and 23 are examples of generic claims which in some cases are limited in subsequent dependent species claims. "A generic claim should include no material element additional to those recited in the species claims, and must comprehend within its confines the organization covered in each of the species." (MPEP 806.04(d))

These generic claims cover two of more mutually exclusive species (i.e. matrix-enhancing molecules) and read on what is comprehended in the ensuing species claims. The Patent and Trademark Office defines "species" as specifically different disclosed embodiments of an invention (Chisum 4:12.03[3][a]). Another definition states that the two species must have different structures and modes of action. The species of matrix enhancing molecules listed in the claims are TGFβ, angiotensin II, insulin-like growth factor, and ascorbic acid. These compounds

have different structures and modes of action but are all related as being enhancers of extracellular matrix ***and all fall within the scope of the independent claims***.

The proper action in this application is to require an election of species between TGFβ, angiotensin II, insulin-like growth factor and ascorbic acid. Applicants elect TGFβ.

The Claims are related as Product and Process

The claims are drawn to a method for making a tissue engineering scaffold containing a matrix-enhancing molecule for inducing formation of extracellular matrix (claims 1-9), the scaffold (claims 10-15) and a method of using this scaffold for tissue regeneration (claims 16-23). Each of these groups have been divided further based on the matrix-enhancing molecule, but this is improper since the independent claims are not limited to any one of the species and the examiner has no right to read limitations into the claims that are not present, even for purposes of a restriction requirement. TGFβ, angiotensin II, insulin-like growth factor and ascorbic acid are the different species of matrix-enhancing molecules that can be incorporated into the scaffold ***as defined by the dependent claims; the independent claims currently encompass all matrix-enhancing molecules***. These are all related because they enhance the formation of extracellular matrix (page 6 lines 10-11 of the specification).

The MPEP states "where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are but different definitions of the same disclosed subject matter, varying in breadth or scope of definition." (MPEP 806.03)

The claims to the process of making (claims 1-9); the claims to the scaffold (claims 10-15); and the claims to the method of using (claims 16-23) clearly define single embodiments of an invention.

It is very clearly stated in 37 C.F.R. 1.141(b) "Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctness between the product and process of using the product can be made".

The examiner has cited distinctness between the product and the process of using the product, but not between the product and the process of making the product. The product is not distinct from the process for making it, because the process is not obvious and the product can not be made by another materially different process (MPEP 806.05(f)). In view of 37 C.F.R. 1.141, a three way restriction requirement is also improper.

Examination of all claims 1-23 on the merits is respectfully solicited.

Respectfully submitted,

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I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being facsimile transmitted to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Aisha Wyatt

Date: October 17, 2002